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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

RB 1/22/99

Certified/Return Receipt Requested

Food and Drug Administration
Kansas City District Office
11630 West 80th Street
P.O. Box 15905
Lenexa, Kansas 66285-5905

Telephone: (913) 752-2100

January 15, 1999

WARNING LETTER

Gary S. Summers, Owner
The Fish Market
2518 East 63rd Street
Kansas City, MO 64130

KAN #99-008

Dear Mr. Summers:

An inspection of your firm on October 20 through 22, 1998, by a Food and Drug Administration Investigator from this office revealed fresh buffalo fish and catfish are processed at, and distributed from, your facility under serious deviations from Title 21, Code of Federal Regulations (21 CFR), Part 123. These deviations cause these products to be adulterated within the meaning of Section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act (Act).

As we explained in a previous letter to your firm, the seafood processing regulations, which became effective December 18, 1997, require implementation of a preventive system of food safety controls known as Hazard Analysis Critical Control Point (HACCP). HACCP essentially involves: **(1) identifying food safety hazards that, in the absence of controls, are reasonably likely to occur in your products; and (2) having controls at "critical control points" in the processing operation to eliminate or minimize the likelihood that the identified hazards will occur.**

Our inspection revealed your processing of fresh buffalo fish and catfish deviates from the regulations contained 21 CFR Part 123 as follows:

failure to maintain sanitation monitoring and control records for all days of production [21 CFR 123.11(c)], as evidenced by:

not maintaining the processing plant in a clean and sanitary condition in that there is peeling paint on the walls and ceiling around the processing area sink;

using a cutting board made of wood to process fish on, which cannot be cleaned effectively;

employees not wearing hair restraints while processing seafood products;

the hand washing station in the processing area does not have hand washing sanitizer or towels;

This letter is not intended to be an all-inclusive list of deficiencies at your facility. At the conclusion of the inspection you were issued a Form FDA 483 which is a list of the investigator's observations of deviations noted during the inspection. It is your responsibility to ensure adherence to each requirement of the Act and regulations.

You should know that this serious violation of the law may result in FDA taking regulatory action without further notice to you. These actions include, but are not limited to, seizure and/or obtaining a court injunction against further marketing of your seafood products.

It is necessary for you to take action on this matter now. Please let this office know in writing within fifteen (15) working days from the date you received this letter what steps you are taking to correct the problems. We also ask that you explain how you plan to prevent these violations from happening again. If you need more time, let us know why and when you expect to complete your correction.

Your reply should be sent to Clarence R. Pendleton, Compliance Officer, at the above address.

Sincerely,

W. Michael Rogers
District Director
Kansas City District